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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,838	11/03/2003	David Fikstad	01235-23625	5766

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
03/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/700,838	**Applicant(s)** FIKSTAD ET AL.	
	Examiner Leslie A. Royds	**Art Unit** 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 February 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: *35,59 and 60*.
   Claim(s) rejected: *35,48-52,54-61,65 and 72-82*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

Continuation of 3. NOTE:

Applicant's proposed after-final amendment dated February 11, 2008 will not be entered into the record because the proposed amendments to claims 35 and 59-60 raise new issues that would require further consideration and/or search.

In particular, Applicant proposes amending claims 35 and 59-60 to now specify that the extended period of time over which the composition is formulated to release cilostazol is between 2 and 24 hours. This proposed amendment narrows the scope of the entirety of the claimed subject matter to now require that the release of cilostazol not only be over an "extended" period of time (as previously claimed), but that the release occur specifically over the period of 2 to 24 hours. In other words, further consideration of the presently applied art under 35 U.S.C. 103(a) would be required, as well as an additional assessment of the prior art to determine whether such amendments would obviate the art of record and/or whether additional art would need to be applied.

Note, for the record, that the proposed amendments to overcome the objections and the rejections under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph, would be adequate to obviate the objections and the rejections under such statutes if the proposed after-final amendment was entered into the record.

Accordingly, the proposed after-final amendment of February 11, 2008 will not be entered into the record because it raises new issues that require further consideration and/or search as noted supra, and, therefore, does not materially reduce or simplify the issues for appeal.

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's request for reconsideration of the present application with regard to the objections and rejections under 35 U.S.C. 101, 35 U.S.C. 112, first paragraph, and 35 U.S.C. 103(a) in light of the amendments to the claims proposed and presented in the after-final amendment has been made. In light of the fact that the proposed amendments to the claims will not be entered into the record, and further in view of the fact that the accompanying remarks are solely directed to the obviation of this rejection as a result of the proposed amendments, the remarks are not found persuasive.

For completeness of the record, Applicant's remarks will be considered insofar as they apply to the previously pending set of claims. Applicant's traversal as stated below has been fully and carefully considered, but fails to be persuasive.

Specifically, Applicant argues that Amselem does not teach delivery of cilostazol, or any other active agent, over an extended period of time. Applicant alleges that all of the release profiles of Amselem et al. show immediate release of the active agent and, thus, the reference fails to teach each and every element of the claims.

In response thereto, Applicant's remarks have been noted with regard to the interpretation of the phrase "released over an extended period of time" as recited in, e.g., claims 35 and 59-60, but are not persuasive. Applicant has failed to provide any quantitation of the phrase "extended period of time" such that the specification and/or claims presently rejected sets forth the metes and bounds of what amounts of time over which the active agent may be released would be tolerated by the claimed invention. Though Applicant defines the term "extended period of time" relative to the term "immediate release" by stating that an "extended period of time" is "release over an amount Of time that exceeds the time required for immediate release", Applicant gives no indication as to what degree of release is encompassed by the phrase "immediate release" such that one of skill in the art would be reasonably apprised of the distinction between the two terms. The definition of "immediate release" as providing "release of a drug at a rate which is not significantly modified by the method of drug formulation" provides no clarification on this issue.

In the absence of such disclosure, and further in view of the fact that Figures 1 and 2 of Amselem et al. demonstrate that compositions formulated according to the disclosure release more than 60% of the lipophilic substance within the first 60 minutes of administration, depending upon the formulation used (note that 10 formulations were studied; see Legends of Figures 1 and 2), Applicant has, respectfully, failed to patentably distinguish the instantly claimed composition over that disclosed by the prior art to Amselem et al. because (i) the instant claims fail to specify the length of time over which release of the active agents effected and (ii) there is nothing of record to define what amount of time would be tolerated by the claims such that it would have been clear that the pharmaceutical preparations disclosed by Amselem et al., which provide, e.g., more than 60% release of the lipophilic substance within the first 60 minutes of administration, are excluded from and/or do not meet the instantly claimed invention.

Note that the term "extended release" permits some tolerance absent an explicit definition of the amount of time over which release of a particular amount of the active agent must occur. Where close prior art exists, the burden is on Applicant to establish that the term "extended release" is sufficiently clear to avoid such art. In the instant case, while Applicant has provided a definition of the term "extended release" at p.4-5 of the instant specification, the definition provides no indication or hint as to what amount of drug released over what amount of time constitutes infringement of the instant claims. There is nothing in the specification, prosecution history or prior art that provides any indication as to what amount of time over which release of the active agent must occur to be covered by the phrase "extended release". Absent such information, Applicant has not persuasively distinguished the instant claims over that of the prior art to Amselem et al.

For the reasons set forth supra, and those alredy of record in the Final Office Action dated January 28, 2008, rejection of claims 35, 48-52, 54-61, 65 and 72-82 remains proper and is hereby maintained.